# PEER REVIEW HISTORY

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# **ARTICLE DETAILS**

TITLE (PROVISIONAL)	Let's talk about children evaluation (LTCE) study in northern Finland:
	A multiple group ecologic study of children's health promotion
	activities with a municipal and time-trend design
AUTHORS	Kujala, Veikko; Jokinen, Jaana; Ebeling, Hanna; Pohjola, Anneli

# **VERSION 1 - REVIEW**

REVIEWER	Associate Professor Andrea Reupert Krongold Clinic Monash University,
	Clayton, Australia
REVIEW RETURNED	09-Feb-2017

OFNEDAL COMMENTS	
GENERAL COMMENTS	Thank you for the opportunity to review this paper. It is an important study with implications for other countries. I do however have some serious reservations about the paper which would need to be addressed. I will provide some overall, general feedback first, and then present detailed feedback for each section.
	The paper aims to describe a protocol of a quasi-experimental ecological study using Let's Talk about Children as an intervention across certain areas of Finland. The main issue with the paper is the lack of clarity between the intervention itself (Let's Talk about Children) and what appears to be a substantial implementation study, in which the intervention is embedded across different sectors. How the research team aims to promote and embed the intervention is not clear - indeed in some instances it is almost assumed that different sectors will merely take on the intervention. How the team aims to embed the intervention into services is important given the ecological nature of the protocol which is doing more than merely evaluating an intervention (and an evaluation of the intervention has been done before). Only brief mention is made of the Effective Family Program (on page 4) and more needs to be provided here in terms of what this program is and how it relates to the intervention.
	Likewise, on page 9 in the opening paragraph, it is stated that "at a systems level, the LTC development program also devotes resources to changing the regional child and family health promotion delivery system, building the capacity of that system to maintain LTC activities and to catch risk considerations before they get worse". How do these initiatives occur? Namely, what resources are devoted to the proposed changes, how is capacity promoted and how are "risk considerations" identified?
	It would appear that the LMT play a significant role in the delivery of

the intervention - how will they be engaged and how will their commitment be promoted and sustained?

Hence, I would recommend that the authors (i) clarify the difference between the intervention and the implementation and moreover, (ii) provide more information about the intended implementation strategy.

## Other general issues include:

The standard of written English needs to be tighter and clearer throughout the paper. There are many instances of awkward prose that need to be rectified. Some basic terminology needs to be clarified also - e.g. what do the authors mean by a systems approach? What do the authors mean by an ecological perspective? What do vertical and horizontal actions mean? What does "harmonized incentive structure for operationalizing the actions" mean? When the authors write municipal group what do they mean by that?

Similarly, sometimes Let's Talk is called an approach, sometimes an intervention - this needs to be clarified (and also relates to my opening concern re the difference between the intervention and the implementation).

Some points made throughout the paper need to be referenced e.g. page 4, line 23 - this is only one example however and there are others. Likewise, when the authors discuss capacity building they need to draw on other literature that discusses some of the issues related to this (see in particular page 4). Overall, the paper needs to be situated within the literature with further references cited, outside of Finland.

### Detailed feedback:

In the abstract - methodology - what series of actions was undertaken to promote engagement? Greater clarify is required re the data and participants involved.

Strengths and limitations - I would suggest actually articulating these using specific stem sentences e.g. The strength of this study are ..... The limitations are..... The last point here is most unclear and needs to be rewritten.

page 4 - last paragraph - do these statistics relate to children whose parents have a mental illness or is it more broad than that? I am not clear how this is relevant to the intervention.

Given this is a protocol I would suggest that the lit review needs to finish with specific hypotheses and not merely what the authors anticipate will occur.

Participants - There are several participants including the regions, workers and children - subheadings might make this section clearer. Who are the program coordinators (their role, profession) and what do they coordinate?

page 9: the training sessions will be subsidized using program resources - in what way subsidized? in the same paragraph - how will suitable participants be found and how is "suitable" defined?

on page 10 in the discussion of a universal LTC discussion - who are the parents? What are their presenting issues and how are they identified?

again on page 10. Previous LT trials have been conducted in mental health services - as far as I am aware, so this is a new step offering it in early childhood education and other school settings. There needs to be some discussion as to the rationale of this and fidelity issues with a different workforce.

last sentence on page 10 -surely this refers to the parents of children in those age groups?

page 11 - change the wording of "unwanted" when referring to adverse outcomes. What does it mean to define a population geographically and temporally?

How will intensity of LTC activities be measured? I am not clear about this.

It is pleasing to see that the number of child referrals is considered this is not necessarily a negative thing however and the authors need to consider this in their discussion.

Data sources - how is commitment measured? what questions are asked to measure this along with maintenance, sustainability, and problem solving. Who are the respondents who are supposed to fill these out?

I am assuming that the author team has access to child welfare statistics? How were they able to access these?

Who or what are the anonymous and voluntary classroom people/process that are responsible for gathering the data? The authors indicate that the questionnaire is continuously being developed - why? and in what way? What are the implications of this for their final results?

page 13 re child welfare notifications - on what basis are these notifications made?

There is much data collected on children - how is this matched to their family circumstances, ie parental diagnosis, poverty and so on.

Are parents' diagnoses (including substance abuse disorders) collected? I am unclear what family/parent characteristics are collected.

Re the data of child referrals to psychiatric services - do we know why they are referred? And what their presenting issue is?

page 14 - it is unclear what "home help" measures and why it is important to this study.

page 14; professionals are to keep a record of LTC discussions and a record of network meetings - what incentive is there for them to do this?

page 16 - it is stated that municipal authorities make "autonomous"

decisions regarding the implementation of LTC. Does this mean that they may say no? What are the implications then for the study?
Finally, was the protocol registered? If so, the registration number needs to be reported. Has the trial also commenced? it is unclear when the trial actually started and the time parameters of the current trial. This is also reflected in the tense employed in the paper (sometimes present, sometime past tense).

REVIEWER	Orla Doyle
	University College Dublin, Ireland
REVIEW RETURNED	06-Mar-2017

## **GENERAL COMMENTS**

This paper describes the evaluation protocol for the Let's Talk about Children (LTC) approach which is being implemented in Northern Finland. The study will use a quasi-experimental approach exploiting differences in the timing of the roll-out of the intervention across different municipalities in order to evaluate the effectiveness of the approach in improving child well-being. Overall, this is a good paper, looking at an interesting topic and the authors should be commended for submitting the protocol for this quasi-experimental design for publication. However, I have some questions about the outcome measures, the identification strategy, and general design questions, which if addressed may enhance the clarity of the paper. These are detailed below.

#### General comments

- (i) One of my main concerns with this paper relates to the aims of the intervention and the outcomes to be assessed. The abstract (pp 2) and the aims of the study (pp 5) state that the aim of LTC is to improve 'socio-emotional well-being', however the intervention section (pp 8) states that the aim of the intervention is to prevent 'mental health problems'. One is not the converse of the other. Greater consistency in language use would be appreciated. More importantly, almost all the primary outcomes are measures related to the quality of parenting (e.g. child welfare actions - notifications, intervention, out of home placement) rather than child outcomes (i.e. a measure of mental health and/or well-being). The relationship between child mental health and the parenting outcomes (i.e. welfare actions) should be discussed. Indeed, while it is likely that families who are in contact with welfare services may have children with mental health difficulties, one cannot make this assumption, and working with welfare services may reflect difficulties with parenting rather than difficulties with child mental health issues. Thus, what is the rationale for using these measures as the primary outcomes of the study if the aims of the intervention are to improve child mental health? What are the mechanisms underlying the hypothesis that the intervention will lead to lower child welfare referrals/interventions? Overall, I believe the paper should be clearer in its terminology regarding the primary aims of the intervention.
- (ii) My second main issue with the paper concerns the identification strategy. The evaluation will use a quasi-experimental design which exploits the implementation of the intervention in different municipalities at different points in time. Therefore, if I am interpreting this correctly, they will compare the outcomes of children in municipalities who have received the full intervention to children in

municipalities who have not yet received the full intervention (i.e. may be in the control group, consultation group, training group, etc.). The identification strategy is therefore based on the assumption that either the rollout of the intervention across municipalities is random (to ensure that there are no systematic differences between the municipalities before the intervention begins), or IF there are differences in the characteristics of the municipalities, these differences are unrelated to the primary outcomes, OR these differences can be captured in the statistical models used. The paper includes no information on how the intervention will be rolled out across the municipalities, therefore it is very difficult to assess the validity of their quasi-experimental design. Will municipalities be randomly assigned to receive the intervention? If not, who decides how they are selected? How are the blocks of municipalities formed - will all rural areas be rolled out together? How will you capture differences across the municipalities in your analysis to ensure that differences in child outcomes are not simply capturing differences in municipalities rather than differences induced by the intervention? These are all questions which are not currently addressed in the paper.

- (iii) There should be more references in the Introduction. Many statements are made without providing references to back up these statements, e.g., page 3 lines 32-33; page 3/4 lines 57- line 1; page 4, line 23.
- (iv) There is a lack of clarity about the age ranges included in the study. Page 5, line 39 states that the population of interest is those under the age of 18, while page 7, line 17 as well as Table 1 seems to indicate that the ages included are 0-17 for the child welfare outcomes and 0-22 for the psychiatric referrals. However, the data analysis section on page 16 again refers to ages 0-19.
- (v) The eligibility criteria to take part in the LTC Discussions and LTC Network Meetings are unclear. At one point, the paper states that all parents have the opportunity to take part, does this mean that parents are the ones to initiate the LTC Discussions with the child's teacher/nurse/social worker? Or can the discussion be initiated by the child's teacher etc. if they believe the family will benefit from the intervention? More information about the intervention's eligibility criteria (if any) would be useful. I would basically like to know whether this is a universal or targeted intervention.
- (vi) I have some questions about the data from the School Health Promotion survey which will be used to assess some secondary outcomes. I assume that this data will only be available for a subsample of eligible children? What age are children in grade 8th and 9th in Finland? The texts states that this survey is anonymous, however I assume you will be able to match it to the child's municipality in order to identify whether they are living in an intervention or control municipality? Finally, this data is not mentioned in the abstract.
- (vii) How will the data analysis account for confounders or differences across intervention and control municipalities?
- (viii) The paper does not mention or hypothesis the likely effect size of the intervention on the key outcomes.
- (i) The manuscript needs a thorough proof reading, there are many

missing words and some sentences do not make sense.

Page specific comments

- (i) Abstract: What does the phrase 'process of the renewal' refer to? I cannot find any reference to it in the text.
- (ii) Page 3, strengths and limitation section, states that 100,000 children will be included in the study, while page 16 states there will be 500,000?
- (iii) Page 4, line 14 what does 'vertical and horizontal actions' refer to?
- (iv) Page 4, lines 51-57. Here it would be useful to report the % of children who experience each of the outcomes of the study, rather than including measures which will not be captured in the study.
- (v) Page 6, line 6 what does 'prior municipalities' mean here? As the municipalities have been implementing the intervention since 2012 I assume they are excluded from the study or do they form an 'always' treated group?
- (vi) Page 10, line 8 how many LTC discussion groups are held?
- (vii) Page 11, line 5, the term 'unwanted outcomes' is not typically used in the literature.
- (viii) Page 14, what is the difference between 'home help' described on lines 11-19 and 'home help rate' described on lines 43-54? Perhaps this should be in the same section.

## **VERSION 1 – AUTHOR RESPONSE**

RESPONSES TO Reviewer #1's COMMNETS

Associate Professor Andrea Reupert

Krongold Clinic Monash University, Clayton, Australia

This is an important study with implications for other countries. I do however have some serious reservations about the paper which would need to be addressed. I will provide some overall, general feedback first, and then present detailed feedback for each section.

Response: We thank the reviewer for the comments.

Comment: (i) clarify the difference between the intervention and the implementation. The paper aims to describe a protocol of a quasi-experimental ecological study using Let's Talk about Children as an intervention across certain areas of Finland. The main issue with the paper is the lack of clarity between the intervention itself (Let's Talk about Children) and what appears to be a substantial implementation study, in which the intervention is embedded across different sectors. How the research team aims to promote and embed the intervention is not clear - indeed in some instances it is almost assumed that different sectors will merely take on the intervention. How the team aims to embed the intervention into services is important given the ecological nature of the protocol which is doing more than merely evaluating an intervention (and an evaluation of the intervention has been done before).

Response: We agree with the reviewer. We believe that the implementation of the LTC approach across all different sectors and the description of the LTC practices (LTC discussion and LTC network meeting) is an important issue. For clarity, we revised the relevant section which now reads: "Intervention across all the municipal child and family services. ...

At the local level, the intervention is implemented and co-ordinated by a Local Management Team (LMT). The LMT includes managers of early childhood education, primary schools, health services, and social services. Each LMT is responsible for implementing the LTC approach in the child and family services of the municipality. Each must have a different LMT due to the large number of service units (kindergartens, schools, health and social care centres), and because the units are spread across the whole county. No one LMT is big enough to cover the whole county.

Each municipality has a four-month "municipal engagement phase" prior to the local trainers' training (Figure 2). During this phase, the LMT engages in the LTC intervention practices with the elected member structures, schools and other units. The trainers are then trained in LTC discussion and network meetings. These training sessions are subsidised by programme resources. The LMT coordinates trainers' training by finding suitable participants. The LMT also advertises the LTC activities in local media (e.g., newspapers, posters and leaflets). The local trainers then deliver LTC discussion training sessions to their colleagues in the municipal child and family services units.

Each LMT is given strategic support, as well as a clear framework and timescales for the assessment of the local activities and outcomes. The Oulu University Hospital annually co-ordinates the intervention activities led by the LMT. Furthermore, appropriate specialist support and mentoring is provided to help the LMT in collecting data and sustaining the local units in their LTC intervention activities. All the LMTs are responsible for the implementation and continuity of the universal LTC activities with parents. At the family level, the LTC practices includes universal LTC discussion for parents and an LTC network meeting for parents who need support.

LTC practices for children's health promotion

LTC discussion

This parent-focused method has been described earlier [9]. Briefly, the aim of the LTC discussion is to help parents recognise their children's strengths and vulnerabilities, and to inform them of ways in which to support their children, despite possible family problems. The LTC discussion consists of one or two sessions with the parent or both parents. The child's own teacher, nurse or social worker is also present. The LTC manuals are available in Finnish on the internet for use in early childhood education, primary school, secondary school and all health and social services [9]. When parents bring up a problem that the family is currently facing; for example, poverty, unemployment and housing problems, a further network meeting is offered. If the parents accept, the meeting is organised with the partners that are expected to be able to help the family. LTC network meeting

The LTC network meeting is designed to respond to the different needs of the family on an ecologic base. Depending on these needs, service representatives in addition to the family's own network are invited to the meeting. The aim of the LTC network meeting is to activate all participants to provide the child and the family with support. The meeting offers a joint action forum for the aid and social support required [10].

LTC activities must be measured in order to be implemented. In each municipality, the intervention includes measures on the operational data of LTC discussions and LTC network meetings. From 2015 onwards, aggregated counts of LTC discussions and network meetings have been obtained from each municipality of the Oulu Region. We use a time-series design to compare different LTC-intervention intensity among the age groups of 0–6 years, 7–16 years and 0–22 years."

Comment: (ii) provide more information about the intended implementation strategy.... on page 9 in the opening paragraph, it is stated that "at a systems level, the LTC development program also devotes resources to changing the regional child and family health promotion delivery system, building the capacity of that system to maintain LTC activities and to catch risk considerations before they get worse". How do these initiatives occur? Namely, what resources are devoted to the proposed changes, how is capacity promoted and how are "risk considerations" identified? It would appear that the LMT play a significant role in the delivery of the intervention - how will they be

It would appear that the LMT play a significant role in the delivery of the intervention - how will they be engaged and how will their commitment be promoted and sustained?

Response: We thank the reviewer for pointing out these issues. We revised the relevant section which

#### now reads:

"The primary objective of the LTC intervention is to prevent mental health problems among children and adolescents. We aim to promote health by making changes to modifiable risk conditions, and supportive changes through attributes that help children grow and develop successfully. At a system level, the LTC development programme also devotes resources to changing the regional child and family health promotion delivery system, building the capacity of this system to maintain LTC activities, and to catching risk conditions before they get worse. A regional steering committee has been established by the Council of Oulu Region. The committee functions as ensuring coordinated actions and development. The committee will deliberate on regional establishment issues and challenges, engage with stakeholders, review and comment on progress made and exchange of experience between the municipalities. The steering committee will provide resources and support for initiating the local activities, ultimately aiming to make LTC discussions and network meetings self-sustaining over time."

Comment: Only brief mention is made of the Effective Family Program (on page 4) and more needs to be provided here in terms of what this program is and how it relates to the intervention. Response: We thank the reviewer for pointing this out. We revised the relevant section which now reads:

"LTC was developed for the Effective Family Program, which provided methods for health and social services to support families and children of mentally ill parents. The methods has earlier been tested in mental health clinics to fit the real-life settings of multi-professional child and family services [5-7]. While LTC was initiated in psychiatric services, the present programme will extend the LTC approach to all municipal child and family services."

Comment: The standard of written English needs to be tighter and clearer throughout the paper. There are many instances of awkward prose that need to be rectified. Some basic terminology needs to be clarified also - e.g. what do the authors mean by a systems approach? What do the authors mean by an ecological perspective? What do vertical and horizontal actions mean? What does "harmonized incentive structure for operationalizing the actions" mean? When the authors write municipal group what do they mean by that?

Response: The language editing for the revised manuscript is now made by a native speaker of English.

Comment: Sometimes Let's Talk is called an approach, sometimes an intervention - this needs to be clarified

Response: We have now clarified the terminology (see also response to first comment as mentioned above).

Comment: Some points made throughout the paper need to be referenced e.g. page 4, line 23 - this is only one example however and there are others. Likewise, when the authors discuss capacity building they need to draw on other literature that discusses some of the issues related to this (see in particular page 4). Overall, the paper needs to be situated within the literature with further references cited, outside of Finland.

Response: We would like to thank the reviewer for careful and thorough reading of this manuscript. The present protocol manuscript reports an ongoing research study. Appropriate previous literature is quite scanty, and no relevant systematic review is available. When reporting results, further references will be discussed.

# Detailed feedback:

In the abstract - methodology - what series of actions was undertaken to promote engagement? Greater clarify is required re the data and participants involved.

Response: For clarity, we revised the relevant section which now reads: "A quasi-experimental ecologic study protocol is implemented to evaluate whether universal LTC practices improve children's well-being. In each municipality, a series of measures concerning municipal engagement,

training of personnel, and the LTC activity with parents are conducted in all communal child and family services. Data collection consists of annual online questionnaires for local management groups and the retrieval of information from Finland's population statistics and child welfare statistics. Child and family service data include annual numbers of LTC discussions and LTC network meetings. Outcome measures include annual child welfare notifications, interventions and placements outside the home, and referrals to child and adolescent psychiatric clinics during 2014–2018." Strengths and limitations - I would suggest actually articulating these using specific stem sentences e.g. The strength of this study are ..... The limitations are..... The last point here is most unclear and needs to be rewritten.

Response: Thank you for this point. In the revision, we have changed the wording as follows:

- The LTCE Study's protocol is suitable when intervention is implemented annually in real-life municipalities. By creating a regional database for the LTC results, we can sample over 100 000 children and youths. The merit of such large-scale evaluations is high.
- The LTC approach seeks to better link community services provided to families and to assist families in accessing the support they need.
- Adequately measuring individual-level LTC intervention results is difficult, because the framework of strengths and vulnerabilities applies to both the capacity of individuals and their social and physical ecologies.

page 4 - last paragraph - do these statistics relate to children whose parents have a mental illness or is it more broad than that? I am not clear how this is relevant to the intervention.

Response: Thank you for this point. The statistics relate to Finnish school prevention study. In the revision, we have changed this wording:

"According to Finnish school health promotion study, most children are happy with their lives. Not all of the secondary school-aged children, however, get the best possible start in life: almost 10% of children live in jobless households, 4% see their parents drunk on a weekly basis, 7% report being bullied weekly at school, and 8% have no close friends [8]."

Participants - There are several participants including the regions, workers and children - subheadings might make this section clearer. Who are the program coordinators (their role, profession) and what do they coordinate?

Response: Thank you for this point, we have changed the wording as follows:

"The "Change now. Let's talk about the children in the Council of Oulu Region" programme is coordinated by the Northern Ostrobothnia Hospital District. The programme was planned at both regional and local levels within regional offices, local public sector offices, non-governmental organisations, and other regional partners. The programme co-ordinators guide the activities at the local level. At this local level, the implementers, including municipal employees and relevant community-based partners are all integrated. Interventions are carried out during early childhood education in primary schools, in secondary schools, and in all health and social services." page 9: the training sessions will be subsidized using program resources - in what way subsidized? in the same paragraph - how will suitable participants be found and how is "suitable" defined? Response: We have changed the wording as follows: "These training sessions are subsidised by programme resources and are free for the municipalities and participants. The LMT co-ordinates trainers' training by finding participants having an avid interest in the subject." on page 10 in the discussion of a universal LTC discussion - who are the parents? What are their presenting issues and how are they identified?

Response: Thank you for this point, we have changed the wording as follows: "When parents bring up a problem that the family is currently facing; for example, poverty, unemployment and housing problems, a further network meeting is offered. If the parents accept, the meeting is organised with the partners that are expected to be able to help the family."

again on page 10. Previous LT trials have been conducted in mental health services - as far as I am aware, so this is a new step offering it in early childhood education and other school settings. There needs to be some discussion as to the rationale of this and fidelity issues with a different workforce.

Response: Thank you for this point. In the revised introduction, we attempt to deal with this issue. "The present development programme in the Council of Oulu Region is based on elements of brief psycho-educational discussions with parents (Let's Talk about Children, LTC) [5]. LTC was developed for the Effective Family Program, which provided methods for health and social services to support families and children of mentally ill parents. The methods has earlier been tested in mental health clinics to fit the real-life settings of multi-professional child and family services [5-7]. While LTC was initiated in psychiatric services, the present programme will extend the LTC approach to all municipal child and family services."

last sentence on page 10 -surely this refers to the parents of children in those age groups? Response: This is another good point. Stratified analyses will include age -groups of 0—6, 7—16 and 17—19 years. The last sentence is now revised: "We use a time-series design to compare different LTC-intervention intensity among the age groups of 0—6 years, 7—16 years and 17—19 years." page 11 - change the wording of "unwanted" when referring to adverse outcomes. What does it mean to define a population geographically and temporally?

Response: We have changed the wording of "unwanted" and clarified the sentence. The revised wording is now: "We assess children's unwanted outcomes on the basis of geographically and temporally defined populations."

How will intensity of LTC activities be measured? I am not clear about this.

Response: For clarity, we revised the relevant section which now reads: "In each local unit, each professional who is offering the service, keeps a record of the LTC discussions held. Furthermore, each professional who convenes an LTC network meeting also keeps a record. After each calendar year, all the LMTs that have passed the community engagement phase are contacted by email and online survey form. The aggregated counts of LTC services are reported for each municipal child and family service sector. Data collection is co-ordinated by the office of the Primary Health Care Unit of the Northern Ostorobothnia Hospital District."

Data sources - how is commitment measured? what questions are asked to measure this along with maintenance, sustainability, and problem solving. Who are the respondents who are supposed to fill these out?

Response: For clarity, we revised the relevant section which now reads:

"The follow-up of child and family service development includes items on commitment made by local organisations, local management groups, trainers' training and local training of personnel. Each municipality has a contract in to the LTC approach together with the Council of Oulu Region. Programme maintenance and sustainability includes items on how LTC activities are adopted into the regular activity of all child and family services, and how LTC activities are maintained by local organisations. Problem-solving ability includes how to tackle children's health issues as an activity of its own, and how participants work together to plan actions.

Online questionnaires are sent out by e-mail to each local management group once a year, in January, and the respondents fill in the questionnaire themselves. Additional requests are made until data from each participating municipality are received. Then the intervention phase (control phase, training and implementing phase, and constant actions) is recorded for each municipality at baseline and after each of the four following intervention periods, i.e. calendar year."

I am assuming that the author team has access to child welfare statistics? How were they able to access these?

Response: In Finland, the municipality-specific data are in electronic form and available to SOTKAnet as of 1998. It allows the user to search for indicator data concerning different geographical areas in absolute numbers and percentages.

Who or what are the anonymous and voluntary classroom people/process that are responsible for gathering the data?

Response: As we indicated previously, each professional who is offering an LTC discussion keeps a record of the LTC discussions held in the local classroom unit. Furthermore, each professional who convenes an LTC network meeting also keeps a record.

The authors indicate that the questionnaire is continuously being developed - why? and in what way?

What are the implications of this for their final results?

Response: We use the Finnish cumulative data, which is collected in a nationwide survey. We have now clarified this "In Finland, the nationwide School Health Promotion study monitors the health and well-being of Finnish adolescents. The School Health Promotion study is carried out every other year in March/April. Since 1996, the study has surveyed 8th and 9th graders in comprehensive schools. For example, the questionnaire includes the measures shown in table 2.

The data are gathered via an anonymous and voluntary classroom-administered questionnaire. Although the questionnaire is continuously being developed, most of the questions have remained the same for almost 20 years, to maintain comparability."

page 13 re child welfare notifications - on what basis are these notifications made?

Response: For clarity, the relevant section now reads: "The measures provides the numbers of child welfare notifications filed during a calendar year. The notification is filed in the municipal unit responsible for civic social services. According to the Finnish Child Welfare Act, a child welfare notification is when someone observes or reports circumstances relating to the care and upbringing of a child that may require an assessment regarding the need for child welfare measures. This can be made by phone, in writing or by visiting the municipal office in person.

Are parents' diagnoses (including substance abuse disorders) collected? I am unclear what family/parent characteristics are collected.

Response: No individual data of parents are collected in this ecologic study of children's health promotion activities.

Re the data of child referrals to psychiatric services - do we know why they are referred? And what their presenting issue is?

Response: No individual data of referrals to psychiatric services are collected in the present ecologic study.

page 14 - it is unclear what "home help" measures and why it is important to this study.

Response: Thank you for this point. The home help indicator is not necessary. In the revision, we describe only home help rate.

page 14; professionals are to keep a record of LTC discussions and a record of network meetings - what incentive is there for them to do this?

Response: You raise an important question regarding data collection. We clarity the relevant section now as follows:

"Each LMT is given strategic support, as well as a clear framework and timescales for the assessment of the local activities and outcomes. The Oulu University Hospital annually co-ordinates the intervention activities led by the LMT, that consists of local managers. Furthermore, appropriate specialist support and mentoring is provided to help the LMT in collecting data and sustaining the local units in their LTC intervention activities. All the LMTs are responsible for the implementation and continuity of the universal LTC activities with parents."

page 16 - it is stated that municipal authorities make "autonomous" decisions regarding the implementation of LTC. Does this mean that they may say no? What are the implications then for the study?

Response: This is also an important issue. The study is conducted in a real-life setting, and the differences between municipalities regarding the activity of LTC discussions look likely. However, the differences enable us in comparing data in municipalities with low and high LTC activities.

Finally, was the protocol registered? If so, the registration number needs to be reported. Has the trial also commenced? it is unclear when the trial actually started and the time parameters of the current trial. This is also reflected in the tense employed in the paper (sometimes present, sometime past tense).

Response: This study is not research stipulated in the Medical Research Act, which only applies to medical research involving intervention in the integrity of a person.

RESPONSES TO Reviewer #2's COMMNETS Orla Doyle

# University College Dublin, Ireland

This paper describes the evaluation protocol for the Let's Talk about Children (LTC) approach which is being implemented in Northern Finland. The study will use a quasi-experimental approach exploiting differences in the timing of the roll-out of the intervention across different municipalities in order to evaluate the effectiveness of the approach in improving child well-being. Overall, this is a good paper, looking at an interesting topic and the authors should be commended for submitting the protocol for this quasi-experimental design for publication. However, I have some questions about the outcome measures, the identification strategy, and general design questions, which if addressed may enhance the clarity of the paper. These are detailed below.

Response: Thank you very much for your kind words about our paper. In the following sections, you will find our responses to each of your points and suggestions.

General comments

(i) One of my main concerns with this paper relates to the aims of the intervention and the outcomes to be assessed. The abstract (pp 2) and the aims of the study (pp 5) state that the aim of LTC is to improve 'socio-emotional well-being', however the intervention section (pp 8) states that the aim of the intervention is to prevent 'mental health problems'. One is not the converse of the other. Greater consistency in language use would be appreciated. More importantly, almost all the primary outcomes are measures related to the quality of parenting (e.g. child welfare actions - notifications, intervention, out of home placement) rather than child outcomes (i.e. a measure of mental health and/or wellbeing). The relationship between child mental health and the parenting outcomes (i.e. welfare actions) should be discussed. Indeed, while it is likely that families who are in contact with welfare services may have children with mental health difficulties, one cannot make this assumption, and working with welfare services may reflect difficulties with parenting rather than difficulties with child mental health issues. Thus, what is the rationale for using these measures as the primary outcomes of the study if the aims of the intervention are to improve child mental health? What are the mechanisms underlying the hypothesis that the intervention will lead to lower child welfare referrals/interventions? Overall, I believe the paper should be clearer in its terminology regarding the primary aims of the intervention. Response: We revised the intervention section which now reads: "The primary objective of the LTC intervention is to improve socio-emotional well-being among children and adolescents." The hypothesis is that LTC discussion helps parents to recognise their children's strengths and vulnerabilities, and enables them to support their children, despite possible family problems. The lower proportion of children referrals to child welfare and to psychiatric clinics will take place in municipalities where universal LTC discussions are held. The families who have problems are helped in an earlier stage, before their children have any difficulties.

(ii) My second main issue with the paper concerns the identification strategy. The evaluation will use a quasi-experimental design which exploits the implementation of the intervention in different municipalities at different points in time. Therefore, if I am interpreting this correctly, they will compare the outcomes of children in municipalities who have received the full intervention to children in municipalities who have not yet received the full intervention (i.e. may be in the control group, consultation group, training group, etc.). The identification strategy is therefore based on the assumption that either the rollout of the intervention across municipalities is random (to ensure that there are no systematic differences between the municipalities before the intervention begins), or IF there are differences in the characteristics of the municipalities, these differences are unrelated to the primary outcomes, OR these differences can be captured in the statistical models used. The paper includes no information on how the intervention will be rolled out across the municipalities, therefore it is very difficult to assess the validity of their quasi-experimental design. Will municipalities be randomly assigned to receive the intervention? If not, who decides how they are selected? How are the blocks of municipalities formed - will all rural areas be rolled out together? How will you capture differences across the municipalities in your analysis to ensure that differences in child outcomes are not simply capturing differences in municipalities rather than differences induced by the intervention? These are all questions which are not currently addressed in the paper.

Response: You raise an important question regarding identification strategy.

This ecologic study focuses on the comparisons of groups and the measures are summaries of observations derived from individuals in each group. The underlying goal is to make ecologic inferences about effects on group rates. We assess the ecologic association between the coverage data of LTC discussions and network meetings and the rate of referrals among many age-groups. Thus, the interpretation of estimated effects is enhanced because two types of comparisons are made simultaneously: change over time within groups and differences among groups. Ecologic effects are relevant when evaluating the effects of processes such as LTC approach.

We inserted in the design section as follows: "The rollout of intervention across municipalities is assigned without using randomization. In each intervention area, the selection and timing is based on the agreement between the municipal town manager and the Council of Oulu Region."

Also, in the data analysis: "There are background differences between municipalities. To control for potential confounding, we use we use adjustment for municipal categories."

(iii) There should be more references in the Introduction. Many statements are made without providing references to back up these statements, e.g., page 3 lines 32-33; page 3/4 lines 57- line 1; page 4, line 23.

Response: Thank for you providing these ideas. We now cite more frequently.

(iv) There is a lack of clarity about the age ranges included in the study. Page 5, line 39 states that the population of interest is those under the age of 18, while page 7, line 17 as well as Table 1 seems to indicate that the ages included are 0-17 for the child welfare outcomes and 0-22 for the psychiatric referrals. However, the data analysis section on page 16 again refers to ages 0-19.

Response: Thank you for this point. In the revision, we have clarified this. The ages included are 0-17.

(v) The eligibility criteria to take part in the LTC Discussions and LTC Network Meetings are unclear. At one point, the paper states that all parents have the opportunity to take part, does this mean that parents are the ones to initiate the LTC Discussions with the child's teacher/nurse/social worker? Or can the discussion be initiated by the child's teacher etc. if they believe the family will benefit from the intervention? More information about the intervention's eligibility criteria (if any) would be useful. I would basically like to know whether this is a universal or targeted intervention.

Response: Thank you for this suggestion. In the revision, we have clarified this.

In the end of the Intervention section we added the wording: "All parents are offered the opportunity to take part in an LTC discussion and are shown the structure of the discussion themes. If they agree, they make an appointment with the professional."

(vi) I have some questions about the data from the School Health Promotion survey which will be used to assess some secondary outcomes. I assume that this data will only be available for a subsample of eligible children? What age are children in grade 8th and 9th in Finland? The texts states that this survey is anonymous, however I assume you will be able to match it to the child's municipality in order to identify whether they are living in an intervention or control municipality? Finally, this data is not mentioned in the abstract.

Response: Thank you for this suggestion. In Finland 8th and 9th graders are between ages 14-15. In the revision, we have clarified this. The ecological data of the survey is available by municipalities. (vii) How will the data analysis account for confounders or differences across intervention and control municipalities?

Response: We revised the data analysis section which now reads: "There are background differences between municipalities. To control for potential confounding, we use we use adjustment for municipal categories."

(i) The manuscript needs a thorough proof reading, there are many missing words and some sentences do not make sense.

Response: The language editing for the revised manuscript is now made by a native speaker of English.

Page specific comments

(i) Abstract: What does the phrase 'process of the renewal' refer to? I cannot find any reference to it in

the text.

Response: This is a good point. In the revision, we use process.

(ii) Page 3, strengths and limitation section, states that 100,000 children will be included in the study, while page 16 states there will be 500,000?

Response: In this ecologic study, there is a population 100,000 children will be in the study. For a five year follow-up period there will be 500,000 person-years.

(iii) Page 4, line 14 – what does 'vertical and horizontal actions' refer to?

Response: We revised wording: " ... managerial and field actions"

- (iv) Page 4, lines 51-57. Here it would be useful to report the % of children who experience each of the outcomes of the study, rather than including measures which will not be captured in the study. Response: Thank you for this suggestion. In the revision, we describe the outcome measures tha are available: "In Finland, 6% of children aged 0-17 are subject to a child welfare notification, 5% take part of a child welfare intervention, and 1% have placements outside the home."
- (v) Page 6, line 6 what does 'prior municipalities' mean here? As the municipalities have been implementing the intervention since 2012 I assume they are excluded from the study or do they form an 'always' treated group?

Response: Thank you for raising this point. We have clarified the wording. These municipalities start with municipal's engagement phase.

(vi) Page 10, line 8 – how many LTC discussion groups are held?

Response: The LTC discussion consists of one or two sessions with the parent or both parents.

(vii) Page 11, line 5, the term 'unwanted outcomes' is not typically used in the literature.

Response: We revised the wording "adverse outcomes"

(viii) Page 14, what is the difference between 'home help' described on lines 11-19 and 'home help rate' described on lines 43-54? Perhaps this should be in the same section.

Response: Thank you for this point, this was also a point raised by Reviewer 1. The home help indicator is not necessary. In the revision, we describe only home help rate.

Again, we appreciate all of your insightful comments. We worked hard to be responsive to them. Thank you for taking the time and energy to help us improve the paper.

### **VERSION 2 - REVIEW**

REVIEWER	Associate Professor Andrea Reupert
	Monash University, Australia
REVIEW RETURNED	02-May-2017

GENERAL COMMENTS	Revised Manuscript
	Let's talk about children evaluation (LTCE) study in northern Finland: A multiple group ecologic study of children's health promotion activities with a municipal and time-trend design
	I would like to thank the authors for addressing many of the concerns initially raised. It is a worthwhile paper and one that needs to be circulated.
	Nonetheless, there are still some issues, some similar to those raised earlier, that need to be clarified.
	My concerns re the lack of clarity generally and in particular the confusion between an intervention evaluation and an implementation study still stand though this is perhaps limited to the abstract and in some other less obvious instances in the paper. Accordingly, I have outlined in depth my concerns in the abstract and indicted where else it might be problematic and/or inconsistent.

## Abstract

Opening sentence is too convoluted and needs to be simplified: e.g.

Finland has called for a settings approach (what does this mean?) and change of direction in child and family services (direction towards what?) – two points are being made here – neither of which is clear

So the purpose of the paper is to present "the process and the methods used to evaluate its effectiveness in improving children's socio-emotional well-being" – this indicates that the paper is not an implementation study but an intervention evaluation study – this is somewhat confusing then when other activities (such as municipal engagement and training) are presented that indicate that the study is also concerned with implementation.

I think it would be helpful to indicate that the study documents various systems wide changes (being clear what this means) that then aims to impact of these initiatives on the wellbeing of children. Such a statement clearly combines both the implementation and universal focus of the intervention (which is clearly a strength of the study and is being documented/measured in the study) and the question of whether these initiatives result in changes for children. This dual foci then also helps the reader to appreciate and understand the authors' efforts to document the system wide initiatives alongside children's outcomes.

Not sure what is meant by "universal LTC practices" – in what way universal?

Again lack of clarity around measures is problematic e.g. "a series of measures concerning municipal engagement, training of personnel, and the LTC activity with parents are conducted in all communal child and family services" — what measures were employed? How is the LTC activity measured? What is the "annual online questionnaires for local management groups"? Moreover how do each of these "measures" relate to the overall goals of the paper?

Ensure the goals of the intervention clearly relate to the measures employed to evaluate the intervention. At present it is difficult to see the link between the measures employed and the goals of the study.

The bullet points is the first time the regional data base is mentioned – what is this and why is it important?

## Other feedback

There are still English language problems e.g. "different types of intervention" – should be "interventions" – there are others and these need to be fixed

Page 4 – what are field actions?

Page 5 "According to Finnish school health promotion study, most children are happy with their lives" – this needs a citation. In the same paragraph – why the focus on secondary aged children? Surely the same would apply to younger children?

My earlier concern re the lack of references for a systems approach still stands – please consider drawing on generic literature (such as from Fixsen). This only needs to be brief but would help to situate the study within the broader literature.

Page 5 – it is now stated that "The objective of this paper is to describe the protocol of a quasi-experimental ecologic study with a municipal group and multiple time-series design" – this is not the message outlined in the abstract. I am thinking that the study is an ecological study that looks at the impact of these systems wide changes on children's outcomes – this could be made clearer throughout the paper and in the abstract and the same goals of the paper need to be made consistently throughout the paper.

Page 6 "At this local level, the implementers, including municipal employees and relevant community-based partners are all integrated" – in what way integrated? In the same paragraph – who is delivering the intervention in these various settings?

Page 9: "The LTM coordinates trainers' training by finding participants having an avid interest in the subject". How is an 'avid interest" ascertained?

Page 9 – all parents are offered the intervention – what does ALL mean? Every parent who presents at a particular service? LT was initially developed for parents with mental health concerns – so is the intention to offer the intervention to all parents regardless of their mental health status? Be clear here because this point in particular is important as the efficacy for the intervention with parents without mental health issues has not (yet) been verified.

Will data be collected on the number of offers made to parents and the eventual number of parents who participated? This is an important indicator of the uptake of the intervention – if not collected then consider highlighting as a limitation. Similarly, I appreciate in the last review that many variables that I asked for will not be collected such as parent's mental health status. However, is this a limitation that needs to be identified?

Page 9 "LT activities must be measured to be implemented" – not sure I understand this?

Page 11: "The follow-up of child and family service development includes items on commitment" – this is of interest – how do you measure commitment? While further detail is provided in this paragraph it is still not clear

My initial query has still not been addressed namely - Has the trial also commenced? It is unclear when the trial actually started and the time parameters of the current trial.

Thank you again for your efforts for what promises to be a worthwhile paper. I would encourage you to continue to refine the paper.

Revised Manuscript 4.4.2017

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also commenced? It is unclear when the trial actually started and the
time parameters of the current trial.

REVIEWER	Orla Doyle
	University College Dublin, Ireland
REVIEW RETURNED	21-Apr-2017

### **VERSION 2 – AUTHOR RESPONSE**

RESPONSES TO Reviewer #1's COMMENTS

Associate Professor Andrea Reupert

Krongold Clinic Monash University, Clayton, Australia

COMMENT: I would like to thank the authors for addressing many of the concerns initially raised. It is a worthwhile paper and one that needs to be circulated. Nonetheless, there are still some issues, some similar to those raised earlier, that need to be clarified.

My concerns re the lack of clarity generally and in particular the confusion between an intervention evaluation and an implementation study still stand though this is perhaps limited to the abstract and in some other less obvious instances in the paper. Accordingly, I have outlined in depth my concerns in the abstract and indicted where else it might be problematic and/or inconsistent.

Answer: Thank you very much for your kind words about our paper. In the following sections, you will find our responses to each of your points and suggestions. We are grateful for the time and energy you contributed on our behalf.

COMMENT: Abstract - Opening sentence is too convoluted and needs to be simplified: e.g. Finland has called for a settings approach (what does this mean?) and change of direction in child and family services (direction towards what?) - two points are being made here - neither of which is clear Answer: We rewrote the opening sentence, which now reads: "Making change towards child and family-based and coordinated services is critical to improve quality, outcomes and value." Comment: So the purpose of the paper is to present "the process and the methods used to evaluate its effectiveness in improving children's socio-emotional well-being" - this indicates that the paper is not an implementation study but an intervention evaluation study - this is somewhat confusing then when other activities (such as municipal engagement and training) are presented that indicate that the study is also concerned with implementation. I think it would be helpful to indicate that the study documents various systems wide changes (being clear what this means) that then aims to impact of these initiatives on the wellbeing of children. Such a statement clearly combines both the implementation and universal focus of the intervention (which is clearly a strength of the study and is being documented/measured in the study) and the question of whether these initiatives result in changes for children. This dual foci then also helps the reader to appreciate and understand the authors' efforts to document the system wide initiatives alongside children's outcomes. Answer: We thank the reviewer for pointing out these issues. We revised the relevant section which now reads: "The Let's Talk about Children (LTC) approach, which consists of brief psycho-educational

now reads: "The Let's Talk about Children (LTC) approach, which consists of brief psycho-educational discussions with parents of kindergarten- and school-aged children, has been launched as a municipality-specific program in the Council of Oulu Region. The aim of this paper is to present a protocol of an ecologic follow-up study evaluating the group-specific effects of an intervention about LTC activities in a geographically defined population. The program is designed to promote children's socio-emotional well-being."

Comment: Not sure what is meant by "universal LTC practices" – in what way universal?

Answer: At kindergarten and at school, LTC discussion is offered systematically for all parents of kindergarten- and school-aged children in certain years. This situation involves every parent. We replaced "universal LTC practices" with "systematic LTC practices".

Comment: Again lack of clarity around measures is problematic e.g. "a series of measures concerning municipal engagement, training of personnel, and the LTC activity with parents are conducted in all communal child and family services" — what measures were employed? How is the LTC activity measured? What is the "annual online questionnaires for local management groups"? Moreover how do each of these "measures" relate to the overall goals of the paper? Ensure the goals of the intervention clearly relate to the measures employed to evaluate the intervention. At present it is difficult to see the link between the measures employed and the goals of the study.

Answer: For clarity, we revised the relevant section which now reads:

"A multi-informant setting covers 30 municipalities in northern Finland, and involves all the municipal teachers, social and health care workers. In each municipality a Local Management Team is responsible for implementing the LTC program and collecting the annual data of LTC discussions and network meetings. The outcome data is retrieved from child welfare statistics and hospital registers. The population data, child welfare statistics and referrals to hospitals was retrieved at baseline (2014), and will be retrieved annually. Furthermore, the annual data of LTC discussions and network meetings will be collected of the years 2015-2018."

As described earlier, we have now included a detailed Gannt chart to help frame our study protocol. Also, we have added text to better illustrate the data collection.

Comment: The bullet points is the first time the regional data base is mentioned – what is this and why is it important?

Answer: The Council of Oulu Region is responsible for the arrangement and development of child and family services. There is a need for annual data about LTC activities as well as data about group-specific effects in a geographically defined population.

#### Other feedback

There are still English language problems e.g. "different types of intervention" – should be "interventions" – there are others and these need to be fixed

Page 4 – what are field actions? Answer: operational

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Answer: We have revised the abstract

Page 6 "At this local level, the implementers, including municipal employees and relevant community-based partners are all integrated" – in what way integrated? In the same paragraph – who is delivering the intervention in these various settings?

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Answer: Thank you very much for this insightful comment, which was also referenced by the editor. Again, we appreciate all your insightful comments. We worked hard to be responsive to them. Thank you for taking the time and energy to help us improve the paper.